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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,027	12/17/2001	Arnold M. Escano	ENDOV-51640	2390

24201 7590 08/29/2003

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EXAMINER

BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 08/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/023,027

Applicant(s)

ESCANO, ARNOLD M.

Examiner

Javier G. Blanco

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 6, 11-13 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-10, 14-21, 23, 24 and 27 is/are rejected.
- 7) ☒ Claim(s) 25 and 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 07/07/2003 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION***Election/Restrictions***

1. Applicant's election of **Jacket Guard**: Species A (Figures 4A, 4B); **Grafting System**: Species A (Figure 6); **Superior end of the bifurcated graft**: Species B (Figure 11B); **Apices of superior attachment system**: Species A (Figure 12); **Method of affixing first end of jacket guard**: Species A (gluing); and **Contralateral guidewire**: Species B (configured as a coiled wire) in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Regarding Group I (Jacket Guard), it should be noted that Species A (Figures 4A, 4B) is directed to a balloon catheter assembly comprising an expandable balloon member 30 and a jacket guard 160. Species B (Figures 5A, 5B) is directed to a balloon catheter assembly comprising the expandable balloon member 30 configured as a jacket guard (there is no additional jacket guard). Claim 1 recites that the balloon catheter assembly comprises an elongated shaft 28, an expandable balloon member 30, and a jacket guard 160. Species B is embodied in claims 11-13.

2. Claims 6, 11-13, and 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

Response to Preliminary Amendment

3. Examiner approves substitute Figures 2, 4A, 4B, 5A, 5B, 6-8, 10, 11A, 11B, and 15-18 filed on Paper # 9.

Claim Objections

4. Claims 1, 24, and 27 are objected to because of the following informalities:

- a. In claim 1, line 1, please delete "a" (second occurrence).
- b. In claim 1, line 5, please add a comma (--,--) after "expandable member".
- c. In claim 24, line 5, please delete "and".
- d. In claim 24, line 5, please add a comma (--,--) after "elongate shaft" and also after "expandable member".
- e. In claim 27, line 2, please add a comma (--,--) after "upstream vessel", "first downstream vessel", and "second downstream vessel".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-5, 7-10, 14-21, and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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a. Regarding claim 1, (i) the limitation “whereby the endovascular device and the balloon catheter are housed within the main catheter for intraluminal delivery” (see lines 9-10) is vague and indefinite as to the scope of “endovascular device”. Claims 2-23 do not define what is meant by “endovascular device” (i.e., bifurcated graft by itself, or, bifurcated graft, set of positioning mechanisms, and set of attaching mechanisms); (ii) the limitation “the endovascular device, and the balloon catheter are housed within the main catheter” (see lines 9-10) is vague and renders the claim indefinite since the specification (see for example Figures 2, 3, 4A, 4B, 5A, and 5B) discloses the balloon catheter as placed outside the main catheter.

b. Regarding claim 2, the limitation “wherein the set of positioning mechanisms and the set of attaching mechanisms define an inner diameter measuring less than seven millimeters” (see lines 9-10) is vague and indefinite. According to the specification (see page 27, lines 7-24), main catheter assembly 22 (housing a complete bifurcated grafting system) defines a reduced diameter of 20.7 French (6.9 mm). The claim language of claim 2, lines 9-10 gives the impression that the claimed reduced diameter is defined by the set of positioning mechanisms and the set of attaching mechanisms.

c. Regarding claims 14, 17, and 18, “the set of attaching mechanisms” (see line 1) lacks antecedent basis.

d. Regarding claims 19 and 20, “the set of positioning mechanisms” (see line 1) lacks antecedent basis.

e. Regarding claim 20, “the contralateral member” (see line 2) and “the bifurcated graft” (see line 3) lack antecedent basis. Claims 21 and 23 depend on claim 20.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3-5, 8-10, 14-19, 24, and 27 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Leonhardt et al. (US 5,713,917 A). As seen in Figures 5, 9c, 9d, 10a, 10b, and 11, Leonhardt et al. disclose a system for intraluminally delivering an endovascular device (graft 20 or bifurcated graft 60), the system comprising a main catheter (elongated sheath introducer 106) and a balloon catheter having an elongated shaft (insertion catheter 110), an expandable member (balloon 152), and a pliable or collapsible jacket guard (graft balloon 154) attached proximal to the expandable member (see entire document). It is also possible to consider balloon 152 as the expandable member and tapered head 156 as the jacket guard (see Figure 5). An upstream duct, a first downstream duct, and a second downstream duct form the bifurcated graft (see Figures 3, 4, and 11). Leonhardt et al. also disclose the method for the repairing of a bifurcated vascular vessel (see columns 13-16).

Allowable Subject Matter

9. Claims 2, 7, 20, 21, and 23 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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10. Claims 25 and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Goicoechea et al. (US 5,693,086 A), Leone et al. (US 5,728,068 A), Robichon et al. (US 6,102,940 A), Burkett et al. (US 6,511,503 B1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:00 a.m.-4:30 p.m.), first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


JGB

August 23, 2003


CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
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